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VIA ECF

Hon. Brian M. Cogan, U.S.D.J.
United States District Court
Eastern District of New York
225 Cadman Plaza East
Brooklyn, NY 11201

Re: Ruben Wills v. Microgenics Corporation, et al.
Case No. 1:20-cv-04432-BMC-VMS

Dear Judge Cogan:

Pursuant to Rule III(A)(2) of Your Honor's Individual Practices, Microgenics Corporation and Thermo Fisher Scientific Inc. (collectively, "Defendants" or "Microgenics") respectfully request a pre-motion conference for leave to file a motion to exclude the expert opinion of Robert Swotinsky ("Dr. Swotinsky") and for a *Daubert* hearing.

I. Dr. Swotinsky's Opinion

Plaintiff Ruben Wills' ("Plaintiff" or "Mr. Wills") Complaint is predicated on the singular claim that he suffered unwarranted disciplinary action due to a "false positive" drug test result, which was obtained using an Indiko Plus analyzer and a Buprenorphine II assay supplied by Microgenics to the Department of Corrections and Community Supervision ("DOCCS"). *See* Am. Compl. ¶¶ 84, 85, 87, 90. Plaintiff proffers Dr. Swotinsky's testimony to support the claim that *all* immunoassays, including Microgenics' Buprenorphine II assay, are *inherently unreliable* and *prone to false positives*, necessitating confirmatory testing to ensure accurate results. However, Dr. Swotinsky does not posit that Plaintiff's test result was a "false positive," nor does he suggest, even if it was, that it exceeded Microgenics' Buprenorphine II assay's margin of error.

Instead, Dr. Swotinsky deduced the unreliability of Microgenics' Buprenorphine II assay from a combination of factors, including: (1) testimony from Janice Buechler regarding "many" complaints of "false positive" results; (2) DOCCS' subsequent switch to Microgenics' Buprenorphine I assay in the months following Plaintiff's "false positive" test result on March 28, 2019; (3) Alere's negative confirmation test results in August 2019 on five DOCCS-provided samples (out of a total of 2,905 positive results in 2019); (4) DOCCS' August 19, 2019 directive to cease disciplinary action for positive buprenorphine tests; and (5) scholarly articles published from 2005 to 2019 documenting "false positives" associated with Microgenics' Buprenorphine assays, *excluding the one used for Plaintiff's test in 2019*.

II. Legal Standard

Federal Rule of Evidence 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

III. Dr. Swotinsky is Not Qualified to Opine on the Drug Testing Protocols Used in the Criminal Justice System.

While "a witness [may qualify] as an expert with respect to certain matters or areas of knowledge, it by no means follows that he or she is qualified to express expert opinions as to other fields." *Nimely v. City of New York*, 414 F.3d 381, 399 (2d Cir. 2005). Accordingly, "whether a witness possesses the baseline qualifications to testify about the subject matter at issue goes to his [or her] testimony's admissibility, not its weight." *Martins v. Sherwin-Williams Co.*, No. 22-CV-3520 (BMC), 2023 WL 8788942, at *2 (E.D.N.Y. Dec. 19, 2023).

Dr. Swotinsky's expertise in occupational health does not provide the requisite foundation for understanding the unique drug testing protocols of the criminal justice system, which differ from those employed in workplace settings. Despite the need for specialized knowledge, Dr. Swotinsky did not take steps to familiarize himself with these practices, either through research or other methods, as evidenced by his disregard of the OIG Report, which identified several correctional facilities, that, like DOCCS in 2019, use preliminary immunoassay results without confirmatory testing to discipline inmates. Given Dr. Swotinsky's insufficient experience with, and demonstrated ignorance of, the criminal justice system's drug testing protocols, he is not qualified to offer an expert opinion in the matter at hand and this Court should preclude him from doing so.

IV. Dr. Swotinsky's Opinion on the Drug Testing Protocols of the Criminal Justice System is Not Reliable.

Even if this Court determines that Dr. Swotinsky is qualified to provide expert testimony, the proffered testimony should nevertheless be excluded on the grounds of reliability, as it is not based on sufficient facts or data, founded on reliable principles and methods, or reflective of a reliable application of the principles and methods to the matter at hand. *See* Fed. R. Evid. 702.

First and foremost, Dr. Swotinsky incorrectly applies workplace drug testing standards to correctional facilities. He suggests that, based on general practices in occupational drug testing, confirmation testing should have been performed on Plaintiff's sample. However, this approach does not align with New York State's protocols for inmate drug testing, as outlined in DOCCS Directive 4937 and codified in 7 N.Y. Comp. Codes R. & Regs. § 1020, which do not require confirmatory testing. Therefore, while Dr. Swotinsky's opinion may be relevant in a workplace context, it diverges from the legal standards for correctional facilities that are applicable to this matter.

Furthermore, Dr. Swotinsky's assertion that all immunoassays, including Microgenics' Buprenorphine II assay, are prone to producing "false positive" results and must undergo confirmatory testing for validation, is not supported by empirical data or the standards of accepted scientific principles and methods. Dr. Swotinsky overlooks several studies that confirm the assay's 98% accuracy rate, along with other critical performance metrics such as specificity and sensitivity, which were integral to its FDA approval. See *Allstate Ins. Co. v. Hamilton Beach/Proctor Silex, Inc.*, 473 F.3d 450, 458 (2d Cir. 2007). Additionally, Dr. Swotinsky fails to

consider or rule out other plausible reasons for "false positives" in drug tests, such as the assay's potential cross-reactivity with legally prescribed medications, which is a known and warned-about risk in the package insert.

Last, Dr. Swotinsky's opinion does not reflect a reliable application of recognized principles and methods, as it fails to address whether confirmatory testing would have changed Plaintiff's drug test result, which is crucial to establish damages. Dr. Swotinsky does not provide evidence that Plaintiff's alleged "false positive" result exceeds Microgenics' Buprenorphine II assay's margin of error, which is less than 2%. See *Lynch v. Trek Bicycle Corp.*, 374 F. App'x 204, 207 (2d Cir. 2010). Additionally, Dr. Swotinsky's statement that the test result might be a true positive directly conflicts with Plaintiff's assertion that his result was false. Therefore, Dr. Swotinsky's opinion is both unreliable and insufficient to support Plaintiff's claim of a "false positive" test result.

V. Conclusion

Based on the foregoing, Defendants respectfully request that this Court grant their requests for a pre-motion conference for leave to file a motion to exclude Dr. Swotinsky's expert opinion and for a *Daubert* hearing.

Respectfully Submitted,

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/s/ Christopher R. Carton

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